Notice of Allowability	Application No.	Applicant(s)	
	10/049,306	CATTANEO ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11-23-06.

2. ☒ The allowed claim(s) is/are 1,8,12-16,19,38,40,41 and 46.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ken Sharples on 11/23/06.

The application has been amended as follows:

IN THE SPECIFICATION:

At page 46, line 13, insert --(SEQ ID NO: 2)-- immediately after "RGSRHDL".

Also, the electronic version of the specification contains scanning errors which should be corrected as follows:

At page 9 in Table 1, row 1, delete "Decreas" and substitute --Decrease-- therefor.

At page 9 in Table 1, row 2, delete "Atr phia" and substitute --Atrophia-- therefor.

In the first row of Table 1 on page 10, delete "Ch linergic" and substitute --Cholinergic-- therefor.

At page 46, the paragraph from line 19 to line 26 should read:

--Peptide 18 intraventricular injections. The analysis number of ChAT positive neurons in the basal forebrain of anti-NGF mice revealed a decrease around 40% with respect to transgenic control mice (Fig. 32A,B, Fig. 33D). The intraventricular administration of the phage carrying the peptide 18 restored the number of ChAT

positive neurons in the basal forebrain of the anti-NGF mice to normal values (Fig. 32C, Fig. 33D) while the injection of the peptide binder of anti-NT-3 did not restore the normal values of ChAT-positive neurons (Fig. 32D, Fig. 33D).--

IN THE CLAIMS:

Cancel claims 11, 39, and 42-45.

1. (Currently Amended) A transgenic mouse whose genome comprises transgenes comprising sequences that ~~encoding~~ encode a variable heavy chain and a variable light chain of an NGF-specific ~~anti-NGF~~ antibody or fragment thereof, wherein the expressed transgene products combine to form an antibody or fragment thereof that is specific for NGF and prevents binding of NGF to its receptors, said transgenes being detectably expressed in the mouse by 90 days postnatal, and said mouse having, or being predisposed to the development of~~, an adult neurodegenerative pathology characterized by the presence of~~: (a) abnormally processed amyloid precursor protein, (b) amyloid precursor protein and/or β-amyloid protein plaques in the CNS, (c) hyperphosphorylation of *tau* protein, (d) neurofibrillary tangles in the brain, (e) cholinergic deficit, (f) neuronal loss in the cortex of the brain, and (g) ~~behavioral~~ cognitive deficit.

8. (Currently Amended) A transgenic mouse according to claim 1, wherein the neurodegenerative pathology is present in the ~~aged~~ mouse by 15 to 18 months of age.

38. (Currently Amended) The transgenic mouse of claim 1, that:

(a) is heterozygous for a transgene encoding a variable heavy chain and heterozygous for a transgene encoding a variable light chain of an anti-NGF antibody; and,

(b) produces a fully constituted anti-NGF antibody comprising said variable heavy and light chains that is present in the serum of the mouse at a level of at least 50 ng/ml by postnatal day ~~45~~ 90.

40. (Currently Amended) ~~The tissue of claim 39 which is brain tissue~~ Isolated brain tissue from the mouse of claim 1.

41. (Currently Amended) ~~The tissue of claim 39 which is skeletal tissue~~ Isolated skeletal muscle tissue from the mouse of claim 1.

46. (New) A transgenic mouse whose genome comprises transgenes comprising sequences that encode a variable heavy chain and a variable light chain of an NGF-specific antibody or fragment thereof, wherein the expressed transgene products combine to form an antibody or fragment thereof that is specific for NGF and prevents binding of NGF to its receptors, said transgenes being detectably expressed in the mouse by 90 days postnatal, and said mouse having, or being predisposed to the development of at least two of the following characteristics: (a) abnormally processed amyloid precursor protein, (b) amyloid precursor protein and/or β-amyloid protein plaques in the CNS, (c) hyperphosphorylation of *tau* protein, (d) neurofibrillary tangles in the brain, (e) cholinergic deficit, (f) neuronal loss in the cortex of the brain, and (g) cognitive deficit.

Specification/Drawings Objections

The brief description of Fig. 1 stands objected to because, although panels A-E are described, panel F is not. In the aforementioned interview. Mr. Sharples indicated that the brief description of Panel E on page 17 lines 24-27 was in fact a description of Panel F, and that a description of Panel E had been omitted. The Examiner suggests that the brief description of Panel E should be changed to state "Northern Blot analysis

of the levels of mRNAs specific for chimeric VH and VK chains in brain, kidney, heart, muscle, liver, and testicles" as supported at page 26, lines 15-18 of the specification, and the existing Panel E description should be amended to Panel F. Alternatively a new Figure could be submitted deleting panel E and relabeling panel F as panel E.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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